

REMARKS

Applicants respectfully request reconsideration of the application in view of the following remarks.

Allowable Subject Matter

Applicants gratefully acknowledge the allowance of Claims 1-3 and 6-9.

Rejection of Claims 4 and 5 under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 4 and 5 under 35 U.S.C. § 103(a) as being obvious over Cassella Farbwerke et al. (CA 115:29157), Singh et al. (CA 115:29157) and/or Bogdanowicz-Szwed et al. (CA 136:118356) alone or in combination. Specifically, the Examiner asserts that the references, which teach methyl analogs of compounds of Claims 4 and 5, render those claims obvious because methyl analogs of known compounds are allegedly considered to be obvious variants to one of skill in the art because of their close structural similarity. The Examiner concludes that, absent nonobvious or unexpected properties, the claimed compounds are considered to be obvious variants, wherein the results are predictable.

A *prima facie* case of obviousness under 35 U.S.C. §103(a) can be rebutted upon a showing of a property not possessed by the prior art. *See* In re Papesch, 315 F.2d 381 (CCPA, 1963) ("From the standpoint of patent law, a compound and all its properties are inseparable."). While Applicants do not agree with the position taken by the PTO on the issue of obviousness, Applicants submit that the claimed compounds of the present invention produce results that are functionally quite different from the three prior art references cited by the Examiner.

Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 by Syuzo Satake in which Mr. Satake attests that the prior art references cannot be used as a material for directly obtaining N-monoalkyl-3-hydroxy-3-(2-thienyl)propanamine, which is a useful intermediate in the preparation of Duloxetine (an antidepressant).

Further, Applicants submit herewith a Declaration under 37 C.F.R. § 1.132 by Naoko Takahashi, in which Ms. Takahashi states that the prior art compounds cannot be used as a material for directly obtaining N-monoalkyl-3-hydroxy-3-(2-thienyl)propanamine. The objective

evidence of unexpected properties presented in these two declarations demonstrates that the instant claims are not obvious.

As demonstrated by the instant Declaration of Syuzo Satake, the (Z)-N-monoalkyl-3-oxo-3-(2-thienyl)propenamines in instant Claims 4 and 5 are useful as preparation materials for (S)-N-methyl-3-hydroxy-3-(2-thienyl)propanamine (i.e., (S)-3-methylamino-1-(2-thienyl)-1-propanol), which is a useful intermediate in the preparation of Duloxetine (an antidepressant). See paragraph 7 of Satake Declaration. In contrast, the prior art compounds are unrelated to this synthetic pathway and thus do not possess this distinct property.

The Declaration of Naoko Takahashi provides additional evidence that not only are the prior art compounds functionally unrelated to the claimed compounds, but also that one of skill in the art would consider it impossible to directly or easily produce the variants of the N-monoalkyl-3-hydroxy-3-(2-thienyl)propanamine from the prior art compounds. The Declaration describes searches of the chemical literature conducted in order to determine whether the three prior art compounds can be used as a material for directly obtaining N-monoalkyl-3-hydroxy-3-(2-thienyl)propanamine. See paragraph 4 of Takahashi Declaration. Despite extensive searches using a variety of search terms, no results were found. In contrast, the compounds of Claims 4 and 5, can be used as an intermediate to produce N-monoalkyl-3-hydroxy-3-(2-thienyl)propanamine through hydrogenation. This property could in no way be predicted absent a review of Applicants' present specification. Ms. Takahashi thus concludes that it is impossible to directly or easily produce the variants of the N-monoalkyl-3-hydroxy-3-(2-thienyl)propanamine from the prior art compounds. See paragraph 9 of Takahashi Declaration. As such, the claimed compounds possess unexpected properties that clearly evidence their nonobviousness.

Because a composition and its properties are considered together in determining obviousness (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)), and because the claimed compounds possess quite unique properties as compared to the prior art compounds, any *prima facie* case of obviousness has been overcome. See, e.g., *M.P.E.P.* §2144.09 (citing *Papesch*) and *M.P.E.P.* §716.02 - §716.02(g). Accordingly, Applicants respectfully request withdrawal of the rejection.

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No Disclaimers or Disavowals


Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: 
Brent C. Moore
Registration No. 55,461
Agent of Record
Customer No. 20995
(619) 235-8550

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